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.RADEMARKS

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/392,934	10/28/96	SMITH R	01-3033

EXAMINER	
SCHWADRON, R	
ART UNIT	PAPER NUMBER
1644	14

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MARK DELUCA
WOODCOCK WASHBURN KURTZ MACKIEWICZ & NOR
ONE LIBERTY PLACE
46TH FLOOR
PHILADELPHIA, PA 19103

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/392,934	Smith et al.
Examiner	**Art Unit**
Ron Schwadron, Ph.D.	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 4/13/2001 and 8/1/2001

2a)☒ This action is **FINAL.** 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31, 34, and 37-50* is/are pending in the application.

4a) Of the above, claim(s) 45-50 is/are withdrawn from consideratio

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 31, 34, 37-44 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some* c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)

16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18)☐ Interview Summary (PTO-413) Paper No(s). _____

19)☐ Notice of Informal Patent Application (PTO-152)

20)☒ Other: PTOL 206

1. Newly submitted claims 45-50 are directed to nonelected species as per the previously enunciated restriction requirement. All of said peptides contain the nonelected peptides recited in original claim 1.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 45-50 are withdrawn from consideration as being directed to a non-elected species. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Claims 31,34,37-44 are under consideration. Claims 1-30,32,33,35,36 have been cancelled.

RESPONSE TO APPLICANTS ARGUMENTS

3. The declaration filed 10/2/2000 has been received and is free of errors.

4. The petition to waive extension fees has been granted (see enclosed communication).

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 31 and 42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for

the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

The specification does not disclose how to use the instant invention for the therapy of EBV related disease in vivo in humans. The claimed pharmaceutical composition is disclosed in the specification as used for the treatment of EBV related disease in vivo in humans. Applicant has not enabled the breadth of the claimed invention in view of the teachings of the specification because the use for the instant invention disclosed in the specification is the in vivo treatment of disease in humans. The state of the art is such that is unpredictable in the absence of appropriate data as to how the instant invention could be used for the treatment of disease in vivo in humans. The specification provides no working examples indicating that the method of the instant invention can be used for the treatment of human disease. Jackman et al. teaches that there is currently no available vaccine for treatment of EBV related disease in humans (see abstract). Jackman et al. teach that in order to establish whether an EBV related protein would even be tested to determine that said protein could be used to treat EBV related disease in humans, that it was necessary to obtain appropriate in vivo data in an appropriate in vivo preclinical model such as cottontop tamarins (eg. see page 660, second column). The specification supplies no in vivo data in any animal model indicating that the claimed invention can be used to treat EBV related disease in humans. It appears that undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification. See In re Wands 8 USPQ2d 1400(CAFC 1988).

Regarding applicants comments, Jackman et al. teaches that there is currently no available vaccine for treatment of EBV related disease in humans (see abstract). Jackman et al. teach that in order to establish whether an EBV related protein would even be tested to determine that said protein could be used to treat EBV related disease in humans, that it was necessary to obtain appropriate in vivo data in an appropriate in vivo preclinical model such as cottontop tamarins (eg. see page 660, second column). Jackman et al. teach that in order to even be considered as a potential vaccine candidate a particular vaccine must be capable of eliciting a particular titer of antibody in vivo (eg. see page 666, second column, last paragraph). Furthermore, Jackman et al. indicate that even based on the in vivo data disclose in their publication that, "It remains to be seen whether MSTOP gp350 will be capable of eliciting a sufficient immune response to protect against EBV related diseases in humans.". The instant discloses no in vivo data in any model showing the ability of the claimed peptides to treat human disease.

7. Claims 31,34,37-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "25 amino acids or less" in claim 37. Applicant has not indicated where in the specification said limitation finds support. The claimed peptide encompasses peptides that are less than 15 amino acids (eg. fragments of the peptide recited in claim 37) and there is no support in the specification as originally filed for such fragments or polymers of such fragments. There is no written description of the scope of the claimed invention in the specification as originally filed (eg. the claimed invention constitutes new matter).

There is no support in the specification as originally filed for the polypeptide of claim 41. Applicant has indicated that said peptide finds support in the specification, pages 8 and 9. The specification, pages 8 and 9 discloses polymers of the claimed peptides. However, there is no disclosure of the identity of said polymers or that said polymers have the particular features recited in claim 41. For example, there is no disclosure in the specification of polymers that contain 3 or 4 of the peptides recited in claim 41. There is no disclosure in the specification that a particular amount of any particular peptide is used in combination with a particular amount of any other peptide in order to produce a polymer. There is no disclosure in the specification that a particular multimer is used in a particular combination as per "r" in said formula. There is also no disclosure in the specification that "n +o+p+q=1-1000" or that "(n+ o+p+q) x r=1-1000". Furthermore, the claimed peptide encompasses polymers ~~containing~~ containing fragments of the peptides recited in the claims that are less than 15 amino acids (eg. fragments of the peptides recited in claim 37). There is no written description of the scope of the claimed invention in the specification as originally filed (eg. the claimed invention constitutes new matter).

8. Regarding the application of prior art, for the same reasons that the instant invention constitutes new matter, the claimed inventions are not entitled to priority to the parent applications to which the instant invention claims priority.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. The rejection of claims 31 and 34 under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter is ~~with drawn~~ withdrawn in view of applicants arguments and related documents submitted in the amendment filed 8/1/2000.

11. Claims 31,34,37-44 stand rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al. WO 94/06470 for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

Smith et al. teach the claimed invention (see claims 1,31,34,36).

Regarding applicants comments, for the same reasons that the instant invention constitutes new matter, the claimed inventions are not entitled to priority to the parent applications to which the instant invention claims priority.

12. Claims 37,40,41,44 are rejected under 35 U.S.C. 102(b) as being anticipated by Pothen et al.

Pothen et al. teach the claimed peptide (see Table 1).

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644

1600
GROUP 1600
PRIMARY EXAMINER
RONALD B. SCHWADRON

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address : COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

08/392,934

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EXAMINER	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED:

The decision on the petition filed in the above entitled application is as follows:

☐ Delay in Prosecution Held Unavoidable (35 U.S.C. 133),

Petition Granted _____

☐ Delayed Payment of Issue Fee Accepted (35 U.S.C. 151),

Petition Granted _____

☒ Petition Granted The petition to waive payment of extension fees filed 4/13/01 is hereby granted.

☐ Petition Denied _____

☐ Petition Dismissed _____

By direction of the Deputy
Assistant Commissioner for Patents

_____

Christina Chan
CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP ~~1800~~ 1640